

ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEETING (68th)

Center for Drug Evaluation and Research, Food and Drug Administration
Marriott Washingtonian Center, Gaithersburg, MD

March 24, 2000

OPEN SESSION

Issue: New Drug Applications (NDA) 21-130, Zyvox® (linezolid) Tablets; NDA 21-131, Zyvox® (linezolid injection) for Injection; and NDA 21-132, Zyvox® (linezolid oral suspension) Oral Suspension.

<u>TIME</u>	<u>TOPIC</u>	<u>SPEAKER</u>
8:30	Call to Order Conflict of Interest Statement	Barth L. Reller, M.D., Chairman Kimberly L. Topper, Executive Secretary
8:35	Opening Remarks	Gary Chikami, M.D., Director Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, FDA
8:45	Applicant Presentation	Pharmacia & Upjohn
	Introduction and Microbiology:	Gary Tarpley, Ph.D. Vice President, Discovery Research
	Clinical Pharmacology and Clinical Trial Results	Barry Hafkin, M.D., Director, Clinical Research
	Early Pediatric Studies:	Donald Anderson, M.D., Vice President and Chief Scientific Officer, Research and Development
10:15	Committee Q&A	
10:30	BREAK	
10:45	FDA Presentation	David Ross, M.D., Ph.D. Medical Officer Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, FDA
12:00	Committee Q&A	
12:15	LUNCH	
1:30	Open Public Hearing	
2:30	Committee Discussion	
4:00	BREAK	
4:15	Committee Discussion and Vote	
5:30	Adjourn	

QUESTIONS

1) Community-acquired pneumonia (CAP)

- a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with CAP?
- b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of CAP due to:
 - i) Methicillin-resistant *Staphylococcus aureus* (MRSA)
 - ii) Penicillin-resistant *Streptococcus pneumoniae* (PRSP)

2) Hospital-acquired pneumonia (HAP)

- a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with HAP?
- b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of HAP due to:
 - i) MRSA
 - ii) PRSP

3) Uncomplicated skin and skin structure infections (uSSSI)

- a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with uSSSI?
- b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of uSSSI due to:
 - i) MRSA

4) Complicated skin and skin structure infections (cSSSI)

- a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with cSSSI?
- b) Include in your discussion whether there are sufficient data to support the efficacy of linezolid for the treatment of cSSSI due to:
 - i) MRSA

5) Infections due to vancomycin-resistant enterococci (VRE)

- a) Do the data support the efficacy and safety of linezolid in the treatment of adult patients with infections due to VRE?
- b) What additional study(ies), if any, would the committee recommend?

**ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
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February 24, 2000

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